



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/669,474 Confirmation No. : 4831
Applicant : DOUGLAS G. McNEEL
Filed : September 25, 2003
TC/A.U. : 1614

Docket No. : 011335.52703US
Customer No. : 23911

Title : METHODS AND COMPOSITIONS FOR TREATING
PROSTATE CANCER USING DNA VACCINES

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.97 and 1.98**

Sir:

In accordance with the duty of disclosure under 37 CFR §1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached Form PTO-1449 and/or listed herein and which the Examiner may deem relevant to patentability of the claims of the above-identified application.

The relevance of these references to the subject matter of the present invention is given in the specification of the present invention.

The present Information Disclosure Statement is being filed (1) no later than three months from the application's filing date or (2) before the mailing date of the first Office Action on the merits (whichever is later), and therefore no certification under 37 C.F.R. §1.97(e) or fee under 37 C.F.R. §1.17(p) is required.

Serial No. 10/669,474
Amendment Dated:
Reply to Office Action

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #011335.52703US).

Respectfully submitted,

March 9, 2004



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FORM PTO-1449 Department of Commerce Patent & Trademark Office	Attorney Docket No. 011335.52703US	Serial No. 10/669,474
	Applicant: Douglas MCNEEL	
	Filing Date September 25, 2003	Group 1614
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Sub-Class	Filing Date (if appropriate)
	AA						

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Sub-Class	TRANSLATION	
							Yes	No
	AB							

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AC	Acsadi G. Jiao SS. Jani A. Duke D. Williams P. Chong W. Wolff JA. Direct gene transfer and expression into rat heart in vivo. [Journal Article] <i>New Biologist</i> . 3(1):71-81, 1991 Jan.
✓	AD	Boyer JD. Cohen AD. Vogt S. Schumann K. Nath B. Ahn L. Lacy K. Bagarazzi ML. Higgins TJ. Baine Y. Ciccarelli RB. Ginsberg RS. MacGregor RR. Weiner DB. Vaccination of seronegative volunteers with a human immunodeficiency virus type 1 env/rev DNA vaccine induces antigen-specific proliferation and lymphocyte production of beta-chemokines. [Clinical Trial. Clinical Trial, Phase I. Journal Article] <i>Journal of Infectious Diseases</i> . 181(2):476-83, 2000 Feb.
✓	AE	Budker V. Zhang G. Knechtle S. Wolff JA. Naked DNA delivered intraportally expresses efficiently in hepatocytes. [Journal Article] <i>Gene Therapy</i> . 3(7):593-8, 1996 Jul.
✓	AF	Budker V. Gurevich V. Hagstrom JE. Bortzov F. Wolff JA. pH-sensitive, cationic liposomes: a new synthetic virus-like vector. [Journal Article] <i>Nature Biotechnology</i> . 14(6):760-4, 1996 Jun.
✓	AG	Budker V. Zhang G. Danko I. Williams P. Wolff J. The efficient expression of intravascularly delivered DNA in rat muscle. [Journal Article] <i>Gene Therapy</i> . 5(2):272-6, 1998 Feb.
	AH	Burch PA. Breen JK. Buckner JC. Gastineau DA. Kaur JA. Laus RL. Padley DJ. Peshwa MV. Pitot HC. Richardson RL. Smits BJ. Sopapan P. Strang G. Valone FH. Vuk-Pavlovic S. Priming tissue-specific cellular immunity in a phase I trial of autologous dendritic cells for prostate cancer. [Clinical Trial. Clinical Trial, Phase I. Journal Article] <i>Clinical Cancer Research</i> . 6(6):2175-82, 2000 Jun.
	AI	Cadeddu JA. Partin AW. Epstein JI. Walsh PC. Stage D1 (T1-3, N1-3, M0) prostate cancer: a case-controlled comparison of conservative treatment versus radical prostatectomy. [Journal Article] <i>Urology</i> . 50(2):251-5, 1997 Aug.
	AJ	Chen Y. Webster RG. Woodland DL. Induction of CD8+ T cell responses to dominant and subdominant epitopes and protective immunity to Sendai virus infection by DNA vaccination. [Journal Article] <i>Journal of Immunology</i> . 160(5):2425-32, 1998 Mar 1.
	AK	Cho HJ. Takabayashi K. Cheng PM. Nguyen MD. Corr M. Tuck S. Raz E. Immunostimulatory DNA-based vaccines induce cytotoxic lymphocyte activity by a T-helper cell-independent mechanism.[comment]. [Journal Article] <i>Nature Biotechnology</i> . 18(5):509-14, 2000 May.
	AL	Danko I. Fritz JD. Jiao S. Hogan K. Latendresse JS. Wolff JA. Pharmacological enhancement of in vivo foreign gene expression in muscle. [Journal Article] <i>Gene Therapy</i> . 1(2):114-21, 1994 Mar.
	AM	Davis HL. Whalen RG. Demeneix BA. Direct gene transfer into skeletal muscle in vivo: factors affecting efficiency of transfer and stability of expression. [Journal Article] <i>Human Gene Therapy</i> . 4(2):151-9, 1993 Apr.

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.	



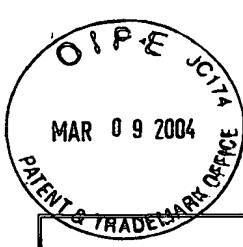
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)			
	AN	Fong L. Ruegg CL. Brockstedt D. Engleman EG. Laus R. Induction of tissue-specific autoimmune prostatitis with prostatic acid phosphatase immunization: implications for immunotherapy of prostate cancer. [Journal Article] <i>Journal of Immunology.</i> 159(7):3113-7, 1997 Oct 1.	
	AO	Fong L. Brockstedt D. Benike C. Breen JK. Strang G. Ruegg CL. Engleman EG. Dendritic cell-based xenoantigen vaccination for prostate cancer immunotherapy. [Clinical Trial. Clinical Trial, Phase I. Journal Article] <i>Journal of Immunology.</i> 167(12):7150-6, 2001 Dec 15.	
	AP	Guinan P. Ray P. Shaw M. Immunotherapy of prostate cancer: a review. [Review] [57 refs] [Clinical Trial. Journal Article. Review] <i>Prostate.</i> 5(2):221-30, 1984	
	AQ	Hartmann G. Weeratna RD. Ballas ZK. Payette P. Blackwell S. Suparto I. Rasmussen WL. Waldschmidt M. Sajuthi D. Purcell RH. Davis HL. Krieg AM. Delineation of a CpG phosphorothioate oligodeoxynucleotide for activating primate immune responses in vitro and in vivo. [Journal Article] <i>Journal of Immunology.</i> 164(3):1617-24, 2000 Feb 1.	
	AR	Irvine KR. Restifo NP. The next wave of recombinant and synthetic anticancer vaccines. [Review] [121 refs] [Journal Article. Review. Review, Tutorial] <i>Seminars in Cancer Biology.</i> 6(6):337-47, 1995 Dec.	
	AS	Iwasaki A. Torres CA. Ohashi PS. Robinson HL. Barber BH. The dominant role of bone marrow-derived cells in CTL induction following plasmid DNA immunization at different sites. [Journal Article] <i>Journal of Immunology.</i> 159(1):11-4, 1997 Jul 1.	
	AT	Lebowitz MS. O'Herrin SM. Hamad AR. Fahmy T. Marguet D. Barnes NC. Pardoll D. Bieler JG. Schneck JP. Soluble, high-affinity dimers of T-cell receptors and class II major histocompatibility complexes: biochemical probes for analysis and modulation of immune responses. [Journal Article] <i>Cellular Immunology.</i> 192(2):175-84, 1999 Mar 15.	
	AU	Lee AH. Suh YS. Sung JH. Yang SH. Sung YC. Comparison of various expression plasmids for the induction of immune response by DNA immunization. [Journal Article] <i>Molecules & Cells.</i> 7(4):495-501, 1997 Aug 31.	
	AV	Mahi-Brown CA. McGuinness RP. Moran F. The cellular immune response to immunization with zona pellucida antigens. [Journal Article] <i>Journal of Reproductive Immunology.</i> 21(1):29-46, 1992 Jan.	
	AW	Mahi-Brown CA. Primate response to immunization with a homologous zona pellucida peptide. [Journal Article] <i>Journal of Reproduction & Fertility - Supplement.</i> 50:165-74, 1996.	
	AX	Manthorpe M. Cornefert-Jensen F. Hartikka J. Felgner J. Rundell A. Margalith M. Dwarki V. Gene therapy by intramuscular injection of plasmid DNA: studies on firefly luciferase gene expression in mice. [Journal Article] <i>Human Gene Therapy.</i> 4(4):419-31, 1993 Aug.	
	AY	McNeel DG. Schiffman K. Disis ML. Immunization with recombinant human granulocyte-macrophage colony-stimulating factor as a vaccine adjuvant elicits both a cellular and humoral response to recombinant human granulocyte-macrophage colony-stimulating factor. [Clinical Trial. Clinical Trial, Phase I. Journal Article] <i>Blood.</i> 93(8):2653-9, 1999 Apr 15.	
	AZ	McNeel DG. Nguyen LD. Storer BE. Vessella R. Lange PH. Disis ML. Antibody immunity to prostate cancer associated antigens can be detected in the serum of patients with prostate cancer. [Journal Article] <i>Journal of Urology.</i> 164(5):1825-9, 2000 Nov.	
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BA	McNeel DG. Disis ML. Tumor vaccines for the management of prostate cancer. [Review] [63 refs] [Journal Article. Review. Review, Tutorial] <i>Archivum Immunologiae et Therapiae Experimentalis.</i> 48(2):85-93, 2000.		
BB	McNeel DG. Nguyen LD. Disis ML. Identification of T helper epitopes from prostatic acid phosphatase. [Journal Article] <i>Cancer Research.</i> 61(13):5161-7, 2001 Jul 1.		
BC	McNeel DG. Nguyen LD. Ellis WJ. Higano CS. Lange PH. Disis ML. Naturally occurring prostate cancer antigen-specific T cell responses of a Th1 phenotype can be detected in patients with prostate cancer. [Journal Article] <i>Prostate.</i> 47(3):222-9, 2001 May 15.		
BD	Mincheff M. Tchakarov S. Zoubak S. Loukinov D. Botev C. Altankova I. Georgiev G. Petrov S. Meryman HT. Naked DNA and adenoviral immunizations for immunotherapy of prostate cancer: a phase I/II clinical trial. [Clinical Trial. Clinical Trial, Phase I. Clinical Trial, Phase II. Journal Article] <i>European Urology.</i> 38(2):208-17, 2000 Aug.		
BE	Murphy GP. Tjoa BA. Simmons SJ. Ragde H. Rogers M. Elgamal A. Kenny GM. Troychak MJ. Salgaller ML. Boynton AL. Phase II prostate cancer vaccine trial: report of a study involving 37 patients with disease recurrence following primary treatment. [Clinical Trial. Clinical Trial, Phase II. Journal Article] <i>Prostate.</i> 39(1):54-9, 1999 Apr 1.		
BF	O'Brien K. Cokkinides V. Jemal A. Cardinez CJ. Murray T. Samuels A. Ward E. Thun MJ. Cancer statistics for Hispanics, 2003. [Journal Article] <i>Ca: a Cancer Journal for Clinicians.</i> 53(4):208-26, 2003 Jul-Aug.		
BG	Oefelein MG. Smith ND. Grayhack JT. Schaeffer AJ. McVary KT. Long-term results of radical retropubic prostatectomy in men with high grade carcinoma of the prostate.[comment]. [Journal Article] <i>Journal of Urology.</i> 158(4):1460-5, 1997 Oct.		
BH	Oldstone MB. Molecular mimicry and immune-mediated diseases. [Review] [102 refs] [Journal Article. Review. Review, Tutorial] <i>FASEB Journal.</i> 12(13):1255-65, 1998 Oct.		
BI	Peyton DK. Ramesh T. Spear BT. Position-dependent activity of alpha -fetoprotein enhancer element III in the adult liver is due to negative regulation. [Journal Article] <i>Proceedings of the National Academy of Sciences of the United States of America.</i> 97(20):10890-4, 2000 Sep 26.		
BJ	Pound CR. Partin AW. Eisenberger MA. Chan DW. Pearson JD. Walsh PC. Natural history of progression after PSA elevation following radical prostatectomy.[comment]. [Journal Article] <i>JAMA.</i> 281(17):1591-7, 1999 May 5		
BK	Raz E. Carson DA. Parker SE. Parr TB. Abai AM. Aichinger G. Gromkowski SH. Singh M. Lew D. Yankaukas MA. et al. Intradermal gene immunization: the possible role of DNA uptake in the induction of cellular immunity to viruses. [Journal Article] <i>Proceedings of the National Academy of Sciences of the United States of America.</i> 91(20):9519-23, 1994 Sep 27.		
BL	Sanda MG. Smith DC. Charles LG. Hwang C. Pienta KJ. Schlom J. Milenic D. Panicali D. Montie JE. Recombinant vaccinia-PSA (PROSTVAC) can induce a prostate-specific immune response in androgen-modulated human prostate cancer. [Journal Article] <i>Urology.</i> 53(2):260-6, 1999 Feb.		
BM	Sgrignoli AR. Walsh PC. Steinberg GD. Steiner MS. Epstein JI. Prognostic factors in men with stage D1 prostate cancer: identification of patients less likely to have prolonged survival after radical prostatectomy.[comment]. [Journal Article] <i>Journal of Urology.</i> 152(4):1077-81, 1994 Oct.		
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BN	Siddall JK. Cooper EH. Newling DW. Robinson MR. Whelan P. An evaluation of the immunochemical measurement of prostatic acid phosphatase and prostatic specific antigen in carcinoma of the prostate. [Journal Article] <i>European Urology</i> . 12(2):123-30, 1986		
BO	Small EJ. Fratesi P. Reese DM. Strang G. Laus R. Peshwa MV. Valone FH. Immunotherapy of hormone-refractory prostate cancer with antigen-loaded dendritic cells.[comment]. [Clinical Trial. Clinical Trial, Phase I. Clinical Trial, Phase II. Journal Article] <i>Journal of Clinical Oncology</i> . 18(23):3894-903, 2000 Dec 1.		
BP	Tang DC. DeVit M. Johnston SA. Genetic immunization is a simple method for eliciting an immune response. [Journal Article] <i>Nature</i> . 356(6365):152-4, 1992 Mar 12.		
BQ	Thomson SA. Sherritt MA. Medveczky J. Elliott SL. Moss DJ. Fernando GJ. Brown LE. Suhrbier A. Delivery of multiple CD8 cytotoxic T cell epitopes by DNA vaccination. [Journal Article] <i>Journal of Immunology</i> . 160(4):1717-23, 1998 Feb 15.		
BR	Tighe H. Corr M. Roman M. Raz E. Gene vaccination: plasmid DNA is more than just a blueprint. [Review] [111 refs] [Journal Article. Review. Review, Academic] <i>Immunology Today</i> . 19(2):89-97, 1998 Feb.		
BS	True LD. Berger RE. Rothman I. Ross SO. Krieger JN. Prostate histopathology and the chronic prostatitis/chronic pelvic pain syndrome: a prospective biopsy study.[comment]. [Journal Article] <i>Journal of Urology</i> . 162(6):2014-8, 1999 Dec.		
BT	von Herrath MG. Oldstone MB. Virus-induced autoimmune disease. [Review] [73 refs] [Journal Article. Review. Review, Tutorial] <i>Current Opinion in Immunology</i> . 8(6):878-85, 1996 Dec.		
BU	Wang B. Ugen KE. Srikantan V. Agadjanyan MG. Dang K. Refaeli Y. Sato AI. Boyer J. Williams WV. Weiner DB. Gene inoculation generates immune responses against human immunodeficiency virus type 1. [Journal Article] <i>Proceedings of the National Academy of Sciences of the United States of America</i> . 90(9):4156-60, 1993 May 1.		
BV	Wolff JA. Malone RW. Williams P. Chong W. Acsadi G. Jani A. Felgner PL. Direct gene transfer into mouse muscle in vivo. [Journal Article] <i>Science</i> . 247(4949 Pt 1):1465-8, 1990 Mar 23.		
BW	Wolff JA. Williams P. Acsadi G. Jiao S. Jani A. Chong W. Conditions affecting direct gene transfer into rodent muscle in vivo. [Journal Article] <i>Biotechniques</i> . 11(4):474-85, 1991 Oct.		
BX	Zhang G. Budker V. Williams P. Subbotin V. Wolff JA. Efficient expression of naked dna delivered intraarterially to limb muscles of nonhuman primates. [Journal Article] <i>Human Gene Therapy</i> . 12(4):427-38, 2001 Mar 1.		
BY	Zhang G. Vargo D. Budker V. Armstrong N. Knechtle S. Wolff JA. Expression of naked plasmid DNA injected into the afferent and efferent vessels of rodent and dog livers.[comment]. [Journal Article] <i>Human Gene Therapy</i> . 8(15):1763-72, 1997 Oct 10.		
BZ	Zou LP. Ma DH. Levi M. Wahren B. Wei L. Mix E. van der Meide PH. Link H. Zhu J. Antigen-specific immunosuppression: nasal tolerance to P0 protein peptides for the prevention and treatment of experimental autoimmune neuritis in Lewis rats. [Journal Article] <i>Journal of Neuroimmunology</i> . 94(1-2):109-21, 1999 Feb 1.		
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